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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,667

06/28/2006

Jean-Philippe Starck

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8348

20306

7590

06/09/2008

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,667	Applicant(s) STARCK ET AL.	
	Examiner SHAWQUIA YOUNG	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 15, 17 and 18 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11, 15, 17 and 18 are currently pending in the instant application.

I. *Response to Arguments*

Applicants' amendment, filed on February 25, 2008, has overcome the rejection of claims 1-11, 15, 17 and 18 under 35 USC 112, second paragraph as being indefinite. The above rejection has been withdrawn.

II. *Rejection(s)*

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

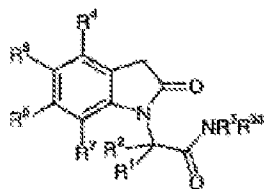
Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. §103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

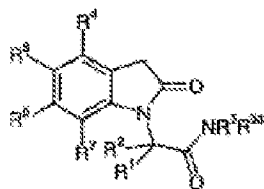
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-11 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Morozov, et al.* (See RN 132382-5, CAPLUS). Applicants claim a



compound of formula  wherein R¹ is hydrogen; R² is hydrogen or C₁₋₂₀ alkyl; R³ is hydrogen, C₁₋₂₀ alkyl, C₄₋₈ cycloalkyl, C₅₋₈ cycloalkenyl, aryl, C₁₋₂₀ alkoxy or a group of formula –W-R⁸; R^{3a} is hydrogen or C₁₋₂₀ alkyl; R⁴ is hydrogen; R⁵ is as defined in claim 1; R⁶ is hydrogen, C₁₋₂₀ alkyl or halogen; R⁷ is hydrogen, C₁₋₂₀ alkyl or halogen, W is C₁₋₁₂ alkylene, –NH– or –NHC(=O); R⁸ is aryl and at least one of R⁵, R⁶ and R⁷ is different from hydrogen when R² is hydrogen, R³ is H or 2,6-diisopropylphenyl and R^{3a} is H.

The Scope and Content of the Prior Art (MPEP §2141.01)

Morozov, et al. teaches 2,3-dihydro-2-oxo-1H-indole-1-acetamide and that it possesses anticonvulsive activity.

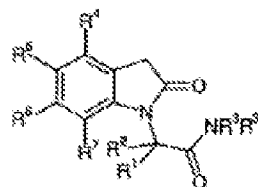
The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Morozov, et al.* and the instant invention is that there is homologous subject matter. The instant claims includes a proviso that at least one of R⁵, R⁶ and R⁷ is different from hydrogen when R² is

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hydrogen, R^3 is H or 2,6-diisopropylphenyl and R^{3a} is H. The definitions of R^5 , R^6 and R^7 include C_{1-20} alkyl (i.e. methyl). The prior art teaches a compound that has no substituents attached to the structure, which does not meet the instant claims' proviso.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)



Applicants are claiming a compound of the formula
wherein specifically at least one of R^5 , R^6 and R^7 is different from hydrogen when R^2 is hydrogen, R^3 is H or 2,6-diisopropylphenyl and R^{3a} is H. The prior art reference of *Morozov, et al.* teaches a similar compound 2,3-dihydro-2-oxo-1H-indole-1-acetamide which does not have any substituents present.

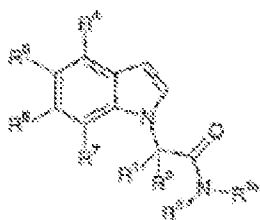
In In re Wood, 582 F.2d 638, 1399 USPQ 137 (CCPA 1978), it was well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. For example, it is obvious to prepare an indol-2-one compound wherein at least one of R^5 , R^6 and R^7 is a methyl group when the art teaches a similar compound wherein only hydrogen atoms are attached to the indole ring (the hydrogen atoms are equivalent to the variables R^5 , R^6 and R^7 in the instant application) with a reasonable expectation of success.

Specifically, an unsubstituted indol-2-one derivative and a methyl substituted indole-2-derivative are considered obvious variants and are unpatentable absent unexpected results. Therefore, it would have been prima facie obvious to one having

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ordinary skill in the art at the time the invention was made to prepare a methyl-substituted indol-2-one derivative based on the teachings of the preferred embodiments in the prior art. A strong prima facie obviousness has been established.

Claims 15 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Macias* (See RN 39597-63-2, CAPLUS). Applicants claim a compound of formula



wherein R^1 is hydrogen; R^2 is hydrogen or C_{1-20} alkyl; R^3 is hydrogen, C_{1-20} alkyl, C_{4-8} cycloalkyl, C_{5-8} cycloalkenyl, aryl, C_{1-20} alkoxy or a group of formula $-W-R^8$; R^{3a} is hydrogen or C_{1-20} alkyl; R^4 is hydrogen; R^5 is as defined in claim 15; R^6 is hydrogen, C_{1-20} alkyl or halogen; R^7 is hydrogen, C_{1-20} alkyl or halogen, W is C_{1-12} alkylene, $-NH-$ or $-NHC(=O)-$; R^8 is aryl and at least one of R^5 , R^6 and R^7 is different from hydrogen when R^2 is hydrogen, R^3 is H or 2,6-diisopropylphenyl and R^{3a} is H.

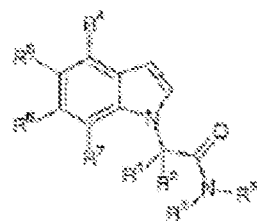
The Scope and Content of the Prior Art (MPEP §2141.01)

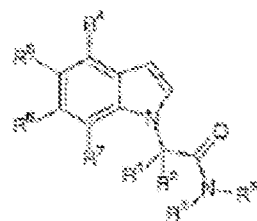
Macias teaches 1H-indole-1-acetamide and its use as a secretory phospholipase A2 inhibitors for the treatment of pain.

The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Macias* and the instant invention is that there is homologous subject matter. The instant claims includes a proviso that at least one of R⁵, R⁶ and R⁷ is different from hydrogen when R² is hydrogen, R³ is H or 2,6-diisopropylphenyl and R^{3a} is H. The definitions of R⁵, R⁶ and R⁷ include C₁₋₂₀ alkyl (i.e. methyl). The prior art teaches a compound that has no substituents attached to the structure, which does not meet the instant claims' proviso.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)



Applicants are claiming a compound of the formula  wherein specifically at least one of R⁵, R⁶ and R⁷ is different from hydrogen when R² is hydrogen, R³ is H or 2,6-diisopropylphenyl and R^{3a} is H. The prior art reference of *Macias* teaches a similar compound 1H-indole-1-acetamide which does not have any substituents present.

In In re Wood, 582 F.2d 638, 1399 USPQ 137 (CCPA 1978), it was well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. For example, it is obvious to prepare an indole-1-acetamide compound wherein at least one of R⁵, R⁶ and R⁷ is a methyl group when the art teaches a similar compound wherein only hydrogen atoms are attached to the indole-1-acetamide ring (the hydrogen atoms are equivalent

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to the variables R⁵, R⁶ and R⁷ in the instant application) with a reasonable expectation of success.

Specifically, an unsubstituted indole-1-acetamide derivative and a methyl substituted indole-1-acetamide derivative are considered obvious variants and are unpatentable absent unexpected results. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to prepare a methyl-substituted indole-1-acetamide derivative based on the teachings of the preferred embodiments in the prior art. A strong prima facie obviousness has been established.

Claim Rejections - 35 USC § 102

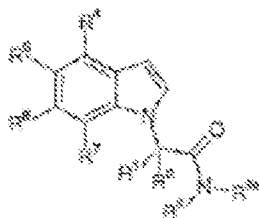
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by *Tius, et al.* (See RN 137641-76-0, CAPLUS), *Ganellin, et al* (RN 17380-11-9, CAPLUS) and *Smith, et al.* (See RN 680994-79-0, CAPLUS). The instant invention claims a product with the

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formula $\text{wherein } R^1 \text{ is hydrogen; } R^2 \text{ is hydrogen or } C_{1-20} \text{ alkyl; } R^3 \text{ is hydrogen, } C_{1-20} \text{ alkyl, } C_{4-8} \text{ cycloalkyl, } C_{5-8} \text{ cycloalkenyl, aryl, } C_{1-20} \text{ alkoxy or a group of formula } -W-R^8; R^{3a} \text{ is hydrogen or } C_{1-20} \text{ alkyl; } R^4 \text{ is hydrogen; } R^5 \text{ is as defined in claim 15; } R^6 \text{ is hydrogen, } C_{1-20} \text{ alkyl or halogen; } R^7 \text{ is hydrogen, } C_{1-20} \text{ alkyl or halogen, } W \text{ is } C_{1-12} \text{ alkylene, } -NH- \text{ or } -NHC(=O); R^8 \text{ is aryl and at least one of } R^5, R^6 \text{ and } R^7 \text{ is different from hydrogen when } R^2 \text{ is hydrogen, } R^3 \text{ is H or 2,6-diisopropylphenyl and } R^{3a} \text{ is H.}$

The *Tius, et al., et al.* reference teaches indole derivatives such as N-methoxy-N-methyl-1H-indole-1-acetamide (See RN 137641-76-0, CAPLUS). This species of compound anticipates the genus compound of the instant invention, wherein the genus structure and its definitions are stated above.

The *Ganellin, et al., et al.* reference teaches indole derivatives such as N,N, α -trimethyl-indole-1-acetamide (See RN 17380-11-9, CAPLUS). This species of compound anticipates the genus compound of the instant invention, wherein the genus structure and its definitions are stated above.

The *Smith, et al., et al.* reference teaches indole derivatives such as N-phenyl-1H-indole-1-acetamide (See RN 680994-79-0, CAPLUS). This species of compound anticipates the genus compound of the instant invention, wherein the genus structure and its definitions are stated above.

III. Objections

Claim Objections

Claims 1, 11 and 17 are objected to because of the following informalities: in claim 1, there is a period at the end of variable R³; in claims 11 and 17, the term “and” needs to be inserted in between the last two compounds.

Dependent Claim Objections

Dependent Claim 7 is objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

IV. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626